

APR - 2 2004

K033864

**510(k) SUMMARY**

Pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, Genzyme Corporation is providing a summary of the safety and effectiveness information available for the OSOM® Trichomonas Rapid Test.

1. Sponsor/Applicant Name and Address:

Genzyme Corporation  
One Kendall Square  
Cambridge, MA 02139

2. Sponsor Contact Information:

E.V. Goorchenko  
Director of Regulatory Affairs  
Phone: 858/777-2614  
FAX: 858/452-3258  
Email: Gene.Goorchenko@genzyme.com

3. Date of Preparation of 510(k) Summary:

December 11, 2003

4. Device Trade or Proprietary Name:

OSOM Trichomonas Rapid Test

5. Device Common/Usual or Classification Name:

Microorganism differentiation and identification device

6. Legally Marketed Devices to which Equivalence is Being Claimed:

Xenotope XenoStrip®-Tv Test (K 020226)

7. Device Description

Intended Use

The OSOM Trichomonas Rapid Test is intended for the qualitative detection of *Trichomonas vaginalis* ("Trichomonas") antigens from vaginal swabs or from the saline solution prepared when making wet mounts from vaginal swabs. This test is intended for use in patients with symptoms of vaginosis/vaginitis or suspected exposure to the Trichomonas pathogen. This device is for use in physicians' offices as well as clinical laboratories.

#### Principle of The Device

The OSOM Trichomonas Rapid Test uses color immunochromatographic, capillary flow, "dipstick" technology with antibodies coated on a nitrocellulose membrane. The test procedure requires the solubilization of Trichomonas proteins from a vaginal swab by placing it in a Sample Buffer. The OSOM Trichomonas Rapid Test is then placed in the Sample Buffer, and the mixture migrates along the membrane surface. If Trichomonas is present in the sample, it will form a complex with the primary anti-Trichomonas antibody conjugated to colored particles (blue). The complex will then be bound by the second anti-Trichomonas capture antibody. The appearance of a visible blue test line together with the red control line indicates a positive result.

#### 8. Comparison of Technological Characteristics of Genzyme OSOM Trichomonas Rapid Test with Legally Marketed Device:

The similarities with, and differences between, the OSOM test and the Xenotope XenoStrip®-Tv device are described in Table 1.

#### 9. Agreement with Wet Mount Microscopy and In-Pouch Trichomonas Culture Device:

The performance of the OSOM Trichomonas Rapid Test was analyzed using a composite reference standard (CRS) calculation (Alonzo, T. & Pepe M., *Statistics in Medicine*, 18: 2987-3003, 1999), which includes the results from wet mount microscopy and culture (InPouch TV™, BioMed Diagnostics Inc., San Jose, CA). In this analysis any sample with a positive result from either wet mount or culture was defined as positive. Accordingly, samples that were negative in both wet mount and culture tests were defined as negative. The results of the comparison of the OSOM Trichomonas Rapid Test using a standard vaginal swab sample to the CRS were:

Sensitivity:	85/102	= 83%
Specificity:	331/335	= 99%
Agreement:	416/437	= 95%

Table 1. Summary of Device Similarities and Differences

	OSOM Trichomonas Rapid Test	Xenotope XenoStrip®-Tv Test
Intended use	Intended for the qualitative detection of <i>Trichomonas vaginalis</i> ("Trichomonas") antigens from vaginal swabs or from the saline solution prepared when making wet mounts from vaginal swabs. This test is intended for use in patients with symptoms of vaginosis/vaginitis or suspected exposure to the Trichomonas pathogen.	Intended for the qualitative detection of <i>Trichomonas vaginalis</i> ("Trichomonas") antigens from vaginal swabs. This test is intended for use in patients with symptoms of vaginosis/vaginitis or suspected exposure to the Trichomonas pathogen.
Assay Format	Lateral flow immunoassay	Lateral flow immunoassay
Specimen	- vaginal swabs - saline solution prepared for wet mount microscopy	- vaginal swabs
Antibodies (labeled and capture)	Mouse monoclonal antibodies	Mouse monoclonal antibodies
Conjugate	Latex	Colloidal gold
Objective Test Line	Blue line	Red line
Internal Control	Yes – red line	Yes – red line



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

APR - 2 2004

Mr. E. V. Goorchenko  
Director of Regulatory Affairs  
Genzyme General Diagnostics  
6659 Top Gun Street  
San Diego, CA 92121

Re: k033864  
Trade/Device Name: OSOM<sup>®</sup> Trichomonas Rapid Test  
Regulation Number: 21 CFR 866.2660  
Regulation Name: Microorganism Differentiation and Identification Device  
Regulatory Class: Class I  
Product Code: JWZ  
Dated: March 16, 2004  
Received: March 17, 2004

Dear Mr. Goorchenko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

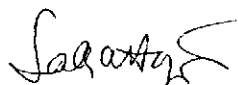
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.  
Director  
Division of Microbiology Devices  
Office of In Vitro Diagnostic Device  
Evaluation and Safety  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K033864

Device Name: OSOM® Trichomonas Rapid Test

Indications For Use: The OSOM® Trichomonas Rapid Test is intended for the qualitative detection of *Trichomonas vaginalis* ("Trichomonas") antigens from vaginal swabs and from the saline solution prepared when making wet mounts from vaginal swabs. This test is intended for use in patients with symptoms of vaginosis/vaginitis or suspected exposure to the Trichomonas pathogen. This device is intended for use in physicians' offices as well as clinical laboratories.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

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510(k) K03 3864